DETAILED ACTION

1. Claims 1-34 are all the pending claims subject to lack of unity restriction.

Lack of Unity: Restriction

2. Restriction is required under 35 U.S.C. 121 and 372.

In assessing whether the requirements of unity of invention of an application are met, identification of the technical features that each solution to a technical problem contributes over the prior art (special technical features) must be made. If then a technical relationship between the solutions, involving one or more of the same technical features, can be recognized, the requirements of unity of invention are said to be met.

The first present claimed invention of the present application relates to a gene construction comprising an expression cassette coding for a signal peptide, a single-domain recombinant antibody and the C- terminal domain of an autotransporter. Such a construct is used for anchoring and expressing a single-domain recombinant antibody on the surface of the outer membrane of a bacteria.

A gene construction comprising an expression cassette coding for a signal peptide, a single-domain recombinant antibody and the C- terminal domain of an autotransporter was already known before the priority date of the present application. For example, VEIGA ESTEBAN ET AL, (JOURNAL OF VIROLOGY, vol. 77, no. 24, December 2003 (2003-12), pages 13396-13398; cited in the IPER filed 7/11/06) discloses the construction of a vector that contains an expression cassette, said

cassette comprising a lac promoter operably linked to a signal peptide PelB, a DNA sequence coding for a single chain Fv protein (VH-VL fusion), an E-tag epitope and the C-terminal transporter domain of the IgAP from Neisseria gonorrhoeae. This construct is used for transforming Escherichia coil cells (gram-negative bacteria) in order to express a single chain recombinant antibody on the surface of the outer- membrane of said bacteria. Thus, the construct contains two different single-domain recombinant antibodies (VH-VL).

3. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. The resulting separate inventions, as presently identified, have been grouped according to the order in which they have been claimed.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-23, drawn to a gene construction comprising:
a) a first nucleic acid sequence containing the nucleotide sequence encoding a signal peptide involved in the passage of proteins across the cell membrane; b) a second nucleic acid sequence containing the nucleotide sequence encoding a single-domain recombinant antibody; and c) a third nucleic sequence containing the nucleotide sequence encoding the C-terminal domain of an autotransporter capable of translocating passenger domain to which it is bound; wherein the 3' end of said first nucleic acid sequence is linked to the 5' end of said second nucleic acid sequence and the 3' end of said second nucleic acid sequence is linked to the 5' end of said third nucleic acid sequence; and a vector comprising the gene construct.

Group II, claim(s) 24-26, drawn to a bacterial cell comprising a gene construction according to claim 1 or an expression vector according to claim 18.

Group III, claim(s) 27-30, drawn to a hybrid protein obtainable by the expression of the nucleic acid sequence contained in the a gene construction according to claim 1 or in an expression vector according to claim 18.

Group IV, claim(s) 31, 33 and 34, drawn to a method of anchoring and expressing a single-domain recombinant antibody on the surface of the outer membrane (OM) of a bacterial cell which comprises culturing the bacterial cell according to claim anyone of claim 24 to 26, under conditions which allow for the production of said single-domain recombinant antibody, its anchoring and expression on the surface of the OM of said bacterial cell in the form of a hybrid protein.

Group V, claim(s) 32, drawn to a method for the specific adhesion of a bacterial cell to an antigen which comprises the steps of: a) transforming a bacterial cell with a gene construction according to claim 1 or with an expression vector according to claim 18 said gene construction or expression vector comprising the nucleotide sequence encoding a single-domain recombinant antibody capable of recognizing said antigen; b) culturing said transformed bacterial cell under conditions which allow for the production of said single-domain recombinant antibody, its anchoring and expression on the surface of the outer membrane (OM) of said cell; and c) contacting the transformed bacterial cell cultured in step b) with said antigen.

4. As no technical features can be distinguished which, in light of the prior art, could be regarded as special technical features on which a unifying concept could be based, there is no single inventive concept underlying the plurality of claimed inventions.

5. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double

patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Election of Species

7. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species (single domain recombinant antibody; Claim 3) are as follows:

a natural or modified heavy chain variable domain (VH) of an antibody,

a natural or modified light chain variable domain (VL) of an antibody,

a natural or modified recombinant camelide antibody (VHIJ),

a humanized recombinant camelide antibody,

a recombinant antibody of a non-camelide animal capable of interacting in the form of a single-domain with its antigen,

an IgNAR single-domain antibody of cartilaginous fish, or

combinations thereof.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. In the event Applicants elect "combinations thereof", they are requested to identify the species for the combination. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise require all the limitations of an allowed generic claim. Currently, the following claim(s) are generic: Claims 1, 2 and 4-23.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynn Bristol whose telephone number is 571-272-6883. The examiner can normally be reached on 8:00-4:00, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lynn Bristol/
Art Unit 1643
Primary Examiner